Food and Drug Administration Center for Food Safety and Applied Nutrition Office of Special Nutritionals

ARMS#



3 - OUTPATIENT

9-10-98

Pt comes to office 90 "bad H/A"

BP 230 & 5min post procaedia 170 & 170 &

100 min post procaedia 150 86

Per Dr. 1000mg Tylend now - then

give of Vicoprofen (pt. to take of her)

Loken she gets home. (PT. deiving).

Bp elevated adnd pt is c/o of ha...denies blurred vision or n,v,.

VS stabale and pt given Procaedia and responded well...ab-le to drive home and continue present bp, eds....

HEENT. Neck supple PERLA FUNDN WNL, neg exudates or hemorrhages or exudates or av nicking noted. Neg JVD or bruits.

Hrr s murmurs neg s3 s4 clicks rubs or heaves.

LUngs CAT Neg rrs

- A: 1. Hyptn un controlled
 - 2. Hypothyroidism New onset.

Abd soft Bs all quads nomasses or bruitsnoted.

NEURO: CN 2- 12 grossly intact DTR's 2/4 briak blat. Extreme: Neg edema or cyanosis or clubbing noted. PSYCH: Ox 3 good spirits and calm after visit.

- 3. Obesity.
- PLAN. 1. Home rest and continue present meds and recheck with my office in the am...
 - 2. to ER if plums should arise during thenight....
 - 3. Call if any questions-

ENDNOTE

Adverse Event Project # 13167

3/26/99 HRB

DOB

9-14-98 MONDAY 1530hrs.

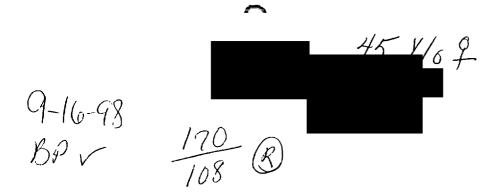
Pt returned the call from this morning and she is doing better since friday...her headaches are substided and she feels fatigue, which I told Fr is normal for starting vasotec BP med...it will pass as your body # L i acclimates to the pills....

PLAN. pt to have thyroid scan on wed in pt to s-e me inoffice on friday am for bp recheck and to discuss labs and to stard SYNTHROID as directed after thryoid scan is completed.

Call if any questions and continue low salt and fat diet. END note.

Adverse Event Project # 13167

3/26/99 HRB



Pt given note for no work this date for then next four days.

cnouseled on effects of bp medsna to restat home and start taking the synthroid today....

Call if any questions.

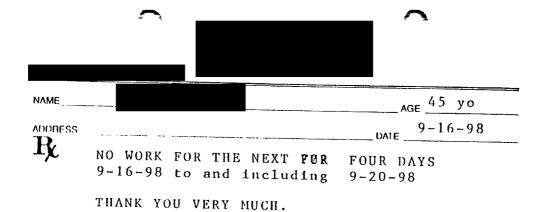
RECHEKC on friday. 9-18-98

Nonumber 5 mg 7/L



Adverse Event Project # 13167

3/26/99 HRB





PT AURHORIZED THIS FORM TO BE FAXED TO HER PLACE OF EMPLOYMENT THIS DATE.

Adverse Event Project # 13167

3/26/99 HRB

9-18-98 45 1/6 9 MKDA 4011000-Up, DT. 254 T.97. P.80 R.16 BP 148 BP 148 (B) LAST WK IN OIT Draw thyrad Panel

145 /98 RT by PHysician.
Pt feeling better and no headaches noted but still feels slightly tired and fatigued...i explained that this is secondary to the norvasc pills acclimating to her system...thsi css sould resouve over time....if it down note weil will change thepikl.

HEENT. Neck supple PERLA NEG NODES. NEG JVD or bruits. Hrr c grade 1/2 /6 SEM neg clicks rubs or heaves.

Lungs CAT Neg rrw.

THYROID SCAN results of Wed reveal No cold nodules and slightly enlarged RT side gland.

Extreme: neg edema.

Pulses 2/4 bilat upper andloer extemetiy.

- A: 1. Hypothyroid ism new onset
 - 2. Hyper tension
 - 3. Obesity.

PLAN. Continue norvasc 10mg per day in divided doses and will recheck bp in 2 weeks and pt to take bp daily and record....for charts in charts.

Call if any questions.

Call it any quebelon

Will repeat

eks. Oct 26th at

END NOTE

Adverse Event Project # 13167

3/26/99 HRB

MEDICAL HISTORY	: : /	Date: 9 1 18 1 98				
		Age Birthda	ate			
Name			Female			
Address .		 -	remaie			
_		Home Phone				
		Work Phone				
Occupation <u>Cashier</u>		Emergency Contact				
·		Phone _				
☐ Single □	☐ Married ☐ Divorce	ed 🗖 Widowed 📮 S	Separated			
If married, spouse's name	NA					
Children's names and ages						
		THE OUDCIANCEC	N No.			
ALLERGIES TO MEDICAT	IONS, X-RAY DYES, OR O	HEK SUBSTANCES	No ☐ Yes			
(If yes, please list name of medici	ne and type of reaction):		·			
			·			
	AND DELUCIN OF OVOTE	140				
PAST MEDICAL HISTORY	AND REVIEW OF SYSTE	M3				
Please circle if you have had pro	blems with or are presently compla	aining of any of the following:				
(High Blood Pressure	Pneumonia	Unexplained weight loss/gain	Skin diseases			
Diabetes	Persistent Cough	Hemorrhoids	Blood disorders			
Cancer	T.B.	Gall bladder disease	Venereal diseases			
(Haart Disease) Mucmur	Hay Fever	Colitis	Anxiety			
Chest Pain / Tightness	Abdominal Discomfort	Hepatitis or jaundice	Depression			
Shortness of Breath	Indigestion	Thyroid diseasa	Anemia			
Swollen Ankles	Nausea	Head or Neck radiation	Alcohol abuse			
Palpitations	Vomiting	Headache	Drug abuse			
Lightheadedness	Constipation	Kidney diseases	Gout			
Frequent Urination	Diarrhea	Kidney stones	Blood transfusions			
Rheumatic Fever	Blood in Stool	Difficulty urinating				
Asthma	Ulcers	Arthritis				
Bronchitis	Change in bowel habits	Low back problems				
Have you over been beenitalized	d (If yes give reason date and	d hospital): yes - High Bloc	d Pressure IThyroad			
9/9/98: Gall Blade	der - 8/86.	, /····	7 2			
-1/4/40 , Gan 11/486	it aface.		`			
Operations: To silveto man	-76; Cyst Removal	(Vaning 1) -75: Gall	Bladder / Appendectomy			
Operations. 7003/76CTOMY	my - 1990 : Planter fa		, , ,			
		Jenes J				
GYNECOLOGIC AND OBS	STETRIC HISTORY					
ILMP <u>/990</u> Last Pap	8/98 Last Mammogram	Last Brea	st Exam <i>8/98</i>			
		monthly Length of	period 5days			
Age at onset of periods	· · · · · · · · · · · · · · · · · · ·		f Birth Control Aysterceton			
Pregnancies						
Prolonged or abnormal bleeding		Advor	se Event Project # 13167			
Leakage of urine:	⊠ No □ Y		1510/cct # 1510/			
Pelvic Pain:	₩ No □	3/20/9	9 HRB cocord			
Abnormal Discharge:	™ No □\	Yes	000007			
History of abnormal Pap Smea	r: 'Da(No 🗆 \	Yes Exhibit	·# 7 Pa / as 3/			
Do you do self breast exams?	□ No ZI	Yes I	# 2 Pg / of 36			
INO AND ON SELL DI ENST EVOLUST						

PLEASE LIST AND SU	JPPLY TH	IE DA	OF:						<u>_</u> _							
Immunization History -	Have Yo	u Had:			Pneum				auon'					When		
Hepatitis B?	ÆY No		When	? #							No			When		
Other?	⊠ No	☐ Yes	When	?	Tetanu	s im	<u>muni</u>	zatio	n?	<u> </u>	No	74	es_	When	<u>? క</u>	 .
When was your last:						,		_								
Cholesterol Check:	8/98		Stool	Check for blo	ood:	7	<u>\$</u>	<u>{</u>	_ Pr	ostat	e Exa	m:				
FAMILY HISTORY Has any member of y	our family	(including	parents	grandparents	s, and sib	lings	s) evel	y had	d the f	ollowi	ng?					
. 11	Iness				Which F	ami	ју Ме	mbe	rs?			Appro	c. Ag	e whe	n Diac	nosed
Cancer (describe type)	Colon	/ liver	•	father (colon)_	maz	her	· (1i	ver	<u>-) </u>	7.	3/	65	<u> </u>	
Thyroid disorder	7	<i>/</i>		Sister												
Hypertension (high blo	od pressi	ure)		brother								90				
Heart Disease				brother								9.	Q			
Diabetes				uncle								3				
Strokes				brother						-		92				
Mental disease (anxiet	ty, depres	sion, etc.)														
Drug or alcohol addicti																
Glaucoma				1/2 5151	Ler-							90)			
Bleeding diseases (he	mophilia,	leukemia,	etc.)													
Other:																
MEDICATIONS (PR	RESCRI	PTIONS	OVE	R-THE-CO	UNTER	, VI	TAM	INS	, HE	RBS	, ET	C.)				
Drug N	lame		1	Dose				Dr	ug Na	ame				D	ose	
Drug N	Iditio			D030	{ }				49							
			_		 .											
			1													
			-	`												
			1													
PREVENTION (O	ptional)															
Do you wear seatbelts	•						No	X	Yes	If no	. why	not?				
Do you wear a bike he				•		<u> </u>	No		Yes							
Do you smoke?						Ø	No				s. ho	w man	у ра	icks pe	r day'	?
Do you drink alcoholic	beverage	es?				Ø	No							r week		
Do you drink coffee?	coks	7.7	IA AU	tched to	calden									ps per		
Do you drink tea?					ue)	00								ps per		
If there is a gun in you	r home, is	it out of c	hildren	s reach & un	loadéd?				Yes							
Do you use drugs? (m						Ø	No		Yes	If ye	s, ex	olain: _				
Have you ever engage	ed in any	activity wh	ich put	vou at risk o	f AIDS?	Ø	No					olain: _				
Do you wish to be test						Ø	No		Yes							
Have you every worke			aints, a	sbestos, or o	other	+	No	X	Yes	If ye	s, ex	olain: _	but	Hery	com	pany
hazardous material?				mbartarii. k		123	NIC		Yes	<u> </u>						
Are you in a relationshislapped, kicked, punc					urt (e.g.		No	_ u	i es A	ı dver	se Ev	vent F	roje	ect # 1	3167	
Do you ever feel afraid						Ø	No			10.610						^~ -
Do you have a "living"						Ø	No	u		26/9	19	HRB		00	000	ນຮ _
Do you have a donor		1					No	Ø	, - D	_Մ ե:ե:	; #	1	D~	1 _£	21	
							_		E	XIIIDI	u#	L	rg_	<u> 2</u> of	<u>بي ر</u>	_

10-21-98 15PV 15PV 16 perling hired WH 253 T. 974 P7Z R. 16 BP 119

Brother & arthritis

Hypefly men.

Pt presents today with good spirits and feeling a little tired from the meds and is still acclimating to the new bp mds....night job still a bit of a problem with sleepinginthe day time. daily bp's are getting closer to nml and elevated bp's are not present anymore. Pr feels better and is eating well and watching her diet and taking her stathed meds as directed.

VS as above . WNL. Stable.

Hent: Neck supple PERLA EOJIsclera white. Fundi WNL.

Neg jvd or bruits. Thyroid not enlarged. neg nodules.

Hrr smurmurs eng w3 s4 clicks rubs or heaves.

Lungs CTA Negrru.

Abd sfot Bs allquadsno masses or bruits. Neg rebond or guarding.

Auro: cn 2- 12 grossly intact, Nml gait and dtr's 2/4 bilat.

Psych: god spirits and mood good. pleasant and please with

bp m,d sns her progress.

A; 1. Hypothyroidiem

2. Hyptn

3. Øbéésítt Obesity, n

LAN: 1. RTC in one omnth for bp recheck and will check thyroid .

2. stay on f any quistions.

END NOTE.

Adverse Event Project # 13167

3/26/99 HRB

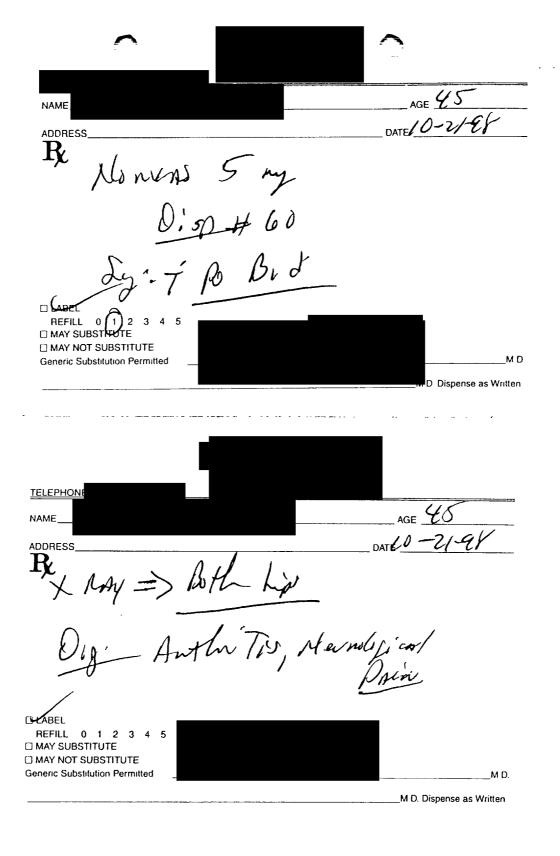
000009

Exhibit # 2 Pg 3 of 3 6

NAME	^		AGE_45	
Re Synth	Laid	0-1-	DATE 10-21-91	
	0124	60		
	7/day	1		
ABEL REFILL 0 1 2 3 MAY SUBSTITUTE MAY NOT SUBSTITUTE Generic Substitution Permi	4 5			M D.
Jeliene Odosination Volum			M D Dispense as	Written
NAME			AGE 45 DATE 0-2/9	
$\mathbf{R}_{\mathbf{k}}$	O Truñ	800 7		
£ (O'syste ig: The	700	Food	-
ITLABEL REFILL 0 1 .2 MAY SUBSTITUTE MAY NOT SUBSTITUT Generic Substitution Perr	E 5			M D
			M D Dispense a	is Written

Adverse Event Project # 13167

3/26/99 HRB



Adverse Event Project # 13167
3/26/99 HRB

Exhibit # 2 Pg 8 of 34

DIAG: Hypothyroidism. 244.9



Adverse Event Project # 13167

3/26/99 HRB

9/20 146/99 - 9/21 $152/115^{-}$ 9/22 157/47 9/23 9/24 147/91 - P 82 9/25 156/99 P-81 9/25 156/98 - P 81 9/27 156/98 - P 81 9/28 168/06 P-99 9/29 188/03 P-77 166/113 79 9/30 19/30

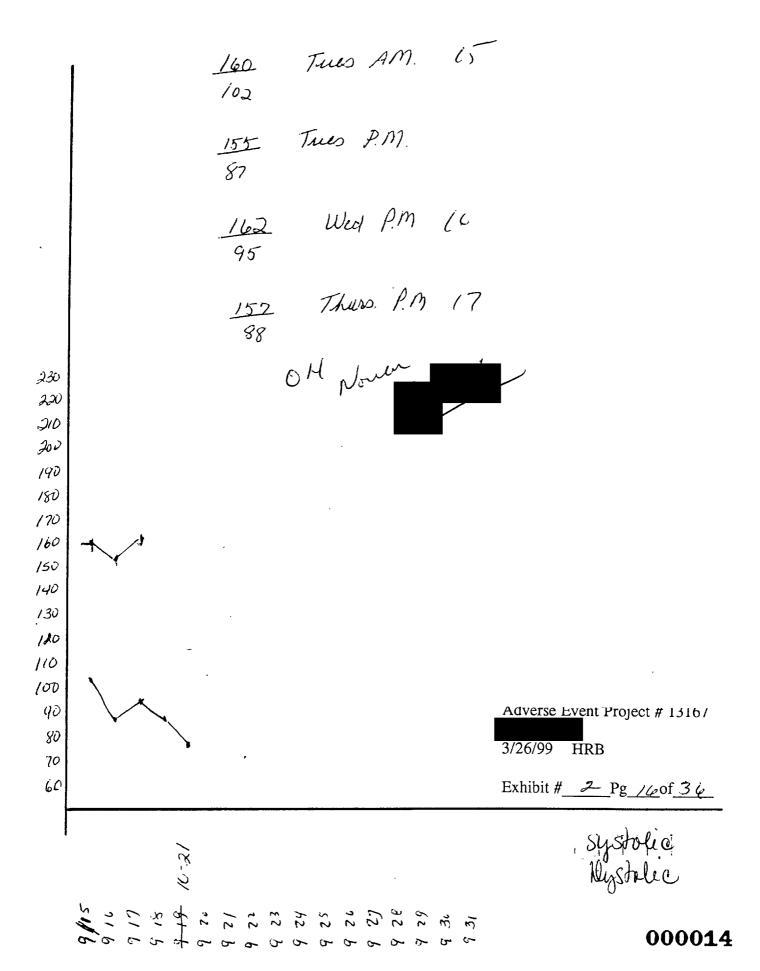
9-28-98 P7 in fou BP V see abour -

10-30 98 Pt Calles riquestra, lab + X-ray 1200 results. TSH not in 194. X Ray hips are normal. Discussed same = p1.

11-3-98 OK lab litter to pt. Repeat Thyroid panel in 3 months, per Dr.

Adverse Event Project # 1316

3/26/99 HRB



PROBLEM LIST

NAME: PPC#: NOB

UVA#:

#	Code #	MAJOR PROBLEMS	Date Enter Date Res	#	Code #	EPISODIC PROBLEMS
				1		
1		HEALTH MAINTENANCE		2		
		HTN Hypothy Roidism Prolecyse ctomy of appendection of 86 Prolecyse ctomy of 86 Proporter fascitia Bilat 98 Pronsile ctomy 76		3		
2		abla N	,	4		
		Hupothupoidism		5		
3		i, i grant and a second		6		
		IP Hysterectomy		7		
4		790		8		
		Plalecyse, ctomy &	***************************************	9		
5		appointection 86		10	······································	
	Š	P Plantar Fascitia		11	·	
6		Bilat 98		12		
		98 Torwile ctorny		13		
7		76,000.76		14		
) Obesity. morbid.		15		
8				16	·	
		}		17		
9				18		
		-		19		
10				20		
		-		21		
11				22		
		-		23		
12		,		24		
_		-		25		
13				26		
		-		27		
14				28	 Adver	se Event Project # 13167
		-		29		
15				30	3/26/9	99 HRB 000015
		-		31	Exhib	it# <u> </u>
16				32		18/601/0



X-RAY REPORT

PATIENT NAME:
HOSPITAL NUMBER:
DATE OF BIRTH:
DATE OF X-RAY:
X-RAY NUMBER:

X-RAY NUMBER: ATTENDING PHYSICIAN: 9-15/9-16-98

DR.

CLINICAL DIAGNOSIS AND/OR PERTINENT HISTORY: HYPERTENSION.

THYROID UPTAKE AND SCAN

392.6 microcuries of I-123 was given. The 24 hour uptake is 39%. Images of the thyroid were obtained. There are no cold nodules. There is slight increased activity over the right lobe compared to the left. The right lobe is larger.

IMPRESSION: 24 HOUR UPTAKE 39%. LARGER RIGHT LOBE THAN THE LEFT WITH SLIGHT INCREASED ACTIVITY OVER THE RIGHT LOBE COMPARED TO THE LEFT. NO COLD NODULES.



D&T: 9-16-98



720/99

Adverse Event Project # 13167

000016

Exhibit # 2 Pg 25 of 36



RADIOLOGY REPORT

PATIENT NAME:
PATIENT NUMBER:

DATE OF STUDY:

10-28-98

ATTENDING PHYSICIAN:

MD

PELVIS/BILATERAL HIPS

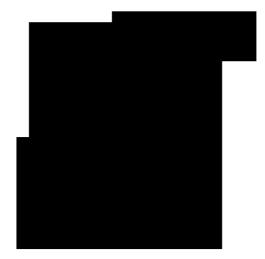
Both hips are intact and in good position. No fractures are seen. There is no significant joint space narrowing in either hip. The bones are well mineralized. The visualized portions of the pelvis are unremarkable. There is no lytic or blastic lesion.

IMPRESSION:

No significant abnormality identified.

D: 10-28-98

T: 10-28-98





Adverse Event Project # 1316

3/26/99 HRB

000017

Exhibit # 2 Pg /8 of 36

